Real-world Performance of the New C3 Gore Excluder Stent-Graft: 1-year Results from the European C3 Module of the Global Registry for Endovascular Aortic Treatment (GREAT)

E.L.G. Verhoeven [a,*], A. Katsargyris [a], P. Bachoo [b], T. Larzon [c], R. Fisher [d], D. Ettles [e], J.R. Boyle [f], J. Brunkwall [g], D. Böckler [i], H.-J. Florek [j], A. Stella [k], P. Kasprzak [l], H. Verhagen [m], V. Riambau [n], on behalf of the GREAT European C3 Module Investigators

[a] Department of Vascular and Endovascular Surgery, Paracelsus Medical University, Nuremberg, Germany
[b] Department of Vascular Surgery, Aberdeen Royal Infirmary, Aberdeen, UK
[c] Department of Cardiothoracic and Vascular Surgery, Örebro University Hospital, Örebro, Sweden
[d] Liverpool Vascular and Endovascular Service, Royal Liverpool University Hospital, Liverpool, UK
[e] Department of Radiology, Hull Royal Infirmary, Hull, UK
[f] Department of Vascular Surgery, Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK
[g] Department of Vascular and Endovascular Surgery, University Clinics, University of Cologne, Cologne, Germany
[i] Department of Vascular and Endovascular Surgery, University Hospital Heidelberg, Heidelberg, Germany
[j] Department of Vascular and Endovascular Surgery, Weisseritztal Kliniken, Freital, Germany
[k] Vascular Surgery Department, University of Bologna, Policlinico S. Orsola-Malpighi, Bologna, Italy
[l] Department of Surgery, Vascular Surgery and Endovascular Surgery, University Hospital, University of Regensburg, Germany
[m] Department of Vascular Surgery, Erasmus University Medical Center, Rotterdam, The Netherlands
[n] Vascular Surgery Division, Department of Cardiovascular Surgery, Thorax Institute, Hospital Clinic, University of Barcelona, Spain

WHAT THIS PAPER ADDS

The C3 Gore Excluder stent-graft has a redesigned deployment mechanism that allows for multiple repositioning, both for level and orientation, prior to final deployment. One of the modules of the GREAT registry was designed to monitor the "real-world" performance of the C3 Gore Excluder. The present report presents the combined experience of 13 European centers with the use of the C3 Gore Excluder on 400 patients. The early results show that repositioning before final stent-graft deployment is feasible, safe, and useful in "real-life" conditions, contributing to precise proximal deployment. Longer follow-up will show whether more precise proximal deployment results in better EVAR durability and reduced need for reintervention.

Objectives: The European C3 module of the Global Registry for Endovascular Aortic Treatment (GREAT) provides "real-world" outcomes for the new C3 Gore Excluder stent-graft, and evaluates the new deployment mechanism. This report presents the 1-year results from 400 patients enrolled in this registry.

Methods: Between August 2010 and December 2012, 400 patients (86.8% male, mean age 73.9 $\pm$ 7.8 years) from 13 European sites were enrolled in this registry. Patient demographics, treatment indication, case planning, operative details including repositioning and technical results, and clinical outcome were analyzed.

Results: Technical success was achieved in 396/400 (99%) patients. Two patients needed intraoperative open conversion, one for iliac rupture, the second because the stent-graft was pulled down during a cross-over catheterization in an angulated anatomy. Two patients required an unplanned chimney renal stent to treat partial coverage of the left renal artery because of upward displacement of the stent-graft. Graft repositioning occurred in 192/399 (48.1%) patients, most frequently for level readjustment with regard to the renal arteries, and less commonly for contralateral gate reorientation. Final intended position of the stent-graft below the renal arteries was achieved in 96.2% of patients. Thirty-day mortality was two (0.5%) patients. Early reintervention ($\leq$30 days) was required in two (0.5%) patients. Mean follow-up duration was 15.9 $\pm$ 8.8 months (range 0–37 months). Late reintervention (>30 days) was required in 26 (6.5%) patients. Estimated freedom from reintervention at 1 year was 95.2% (95% CI 92.3–97%), and at 2 years 91.5% (95% CI 86.8–94.5%). Estimated patient survival at 1 year was 96% (95% CI 93.3–97.6%) and at 2 years 90.6% (95% CI 85.6–93.9%).

* Corresponding author. E.L.G. Verhoeven, Klinikum Nürnberg, Breslauer Strasse 201, 90471 Nürnberg, Germany.
E-mail address: Eric.Verhoeven@klinikum-nuernberg.de (E.L.G. Verhoeven).

1078-5884/$ – see front matter
http://dx.doi.org/10.1016/j.ejvs.2014.04.009

Conclusions: Early real-world experience shows that the new C3 delivery system offers advantages in terms of device repositioning resulting in high deployment accuracy. Longer follow-up is required to confirm that this high deployment accuracy results in improved long-term durability.

Article history: Received 11 February 2014, Accepted 14 April 2014, Available online 28 May 2014
Keywords: Abdominal aortic aneurysm, Endovascular aneurysm repair, Gore Excluder, Repositioning, Proximal deployment

INTRODUCTION

Endovascular aneurysm repair (EVAR) is an accepted alternative to open surgery for the treatment of suitable infrarenal abdominal aortic aneurysms (AAA) with short-term advantages and comparable longer-term outcomes.[1,2] Successful EVAR is highly dependent on suitable proximal anatomy. Hostile infrarenal neck anatomy (short length, severe angulation, and circular thrombus/calcification) have been associated with poorer EVAR short- and long-term outcomes.[3,4]

Since the introduction of EVAR two decades ago, stent-graft manufacturers have been trying to evolve the stent-graft technology aiming to broaden anatomic eligibility, and improve operative and long-term outcomes.[5,6] The manufacturer of the Excluder stent-graft, W.L. Gore (W.L. Gore & Associates, Flagstaff, AZ, USA) has made a number of design improvements to the existing and well-documented Excluder stent-graft, with the most notable involving the modification of the ePTFE fabric, to reduce porosity and fluid transmigration. The redesigned Gore Excluder stent-graft performs well, with proven efficacy and durability.[7–9] Established advantages of the Excluder include flexibility and good adaptation of the graft limbs to complex angulated iliac anatomies.[10] Proximal deployment control however seems somewhat inferior to other stent-graft systems.[11] Therefore, the proximal deployment system was completely redesigned to allow for repositioning prior to final deployment, with the aim to improve the proximal deployment accuracy and aid cannulation of the contralateral gate.

To investigate the real-world performance of the new C3 Excluder stent-graft, a registry was set up by the manufacturer. The European C3 module is part of W.L. Gore's Global Registry for Endovascular Aortic Treatment (GREAT). Herein, are reported the 1-year results of the 400 patients enrolled in the European multicenter, post-market, prospective registry.

PATIENTS AND METHODS

GREAT and patient population in the C3 module

GREAT was set up in an attempt to identify global trends in device usage and actively track long-term device performance and patient outcomes. GREAT aims to collect data as a potential mechanism to provide worldwide exposure on Gore product effectiveness. Moreover, GREAT intends to become a global clinical research organization for investigational product evaluations. One of the modules of GREAT collects and analyzes data regarding the C3 delivery system in Europe.

Between August 2010 and December 2012, consecutive patients treated with the C3 Excluder from 13 European sites were enrolled in the C3 European module of GREAT. To reflect real-world performance of the device, patients treated outside the instructions for use (IFU) were also included in the Registry. Participants were considered to be outside IFU according to the reporting standards if[12]

1. the proximal neck length was less than 1.5 cm. This was defined as the distance between the lowest renal artery and the origin of the aneurysmal dilation of the aorta, and/or
2. the infrarenal neck angle was greater than 60 degrees. Neck angle was defined as the angle between the longitudinal axis of AAA neck and the longitudinal axis of the AAA sac.

All included patients provided written informed consent for their participation in the study. The trial was conducted according to the Declaration of Helsinki and the International Conference on Harmonization (ICH) and Good Clinical Practice (GCP) guidelines, and approved by the ethical committee of each participating institution.

Stent-graft design

The C3 Gore Excluder stent-graft is a third-generation modern device featuring an original design with a flexible, catheter-mounted introduction, and active infrarenal attachment with barbs. The deployment mechanism has been modified into a three-step sequence, which enables positioning of the stent-graft up to three times prior to final release from the delivery catheter.[13] In the first step, the body and contralateral limb are opened. A constraining loop around the body of the graft enables recapturing and repositioning of the stent-graft both for level and orientation. At the second step the constraining wire and loop are removed (after confirmation of correct proximal position). The ipsilateral limb is deployed as a separate third step.

Procedure

All patients had a preoperative stent-graft plan featuring length and diameter of the chosen stent-grafts according to their aortic and iliac dimensions. An oversize of at least 2 mm compared to the aortic inner diameter (10—21% oversizing) and 1 mm compared to the iliac inner diameter (7—25% oversizing) is recommended per IFU. The procedure was performed under local, regional, or general anesthesia and via percutaneous or surgical-cut down access according to operator's preference. Heparin and antibiotic were

administered according to each institution's standard regimen. The need for and details of level and/or orientation repositioning were documented for every procedure. Adjunctive procedures (e.g., proximal cuff extender implantation) needed were also documented. A completion angiogram was routinely performed to document final position of the stent-graft and to exclude endoleak.

Technical success was defined as successful deployment of the stent-graft with no type I/III endoleak, unintentional coverage of visceral aortic branches or internal iliac arteries at the end of the procedure, and with successful removal of the delivery system. Primary conversion was considered a technical failure.

Follow-up

Follow up was accomplished according to the protocol of each institution. No specific imaging tests at particular time points were required. Serious adverse events either related or unrelated to the stent-graft were recorded. Serious endoleak, stent-graft migration, and reintervention required during follow-up were also recorded. The time and cause of death were also documented.

Data collection and processing

Collected data were recorded on a web-based electronic report form (iMedidata, Medidata Worldwide Solutions, Inc., New York, NY, USA) to ensure reliability, and secure authentication and traceability. Data management was performed by the Gore Clinical Research Department (W.L. Gore & Associates). All collected data were reviewed and if missing or inconsistent data were detected, relevant queries were posed to the investigators for resolution.

Monitoring visits were performed at each enrollment site to verify necessary study documents, including signed informed consent for each patient. Consistency between electronically imported data and source documents was also examined.

Statistical analysis

Statistical analysis was performed by the Gore Clinical Research Department. All variables are reported descriptively. Categorical variables are expressed as percentage. Continuous variables are presented as mean ± standard deviation. Cumulative patient survival and freedom from reintervention during follow-up were subjected to Kaplan–Meier analysis. All data were analyzed using statistical SAS software, version 9.2 of the SAS System for Windows (Copyright 2002–2008 by SAS Institute INC., Cary, NC, USA).

RESULTS

Baseline data

Between August 2010 and December 2012, 400 consecutive patients (86.8% male, mean age 73.9 ± 7.8 years) from 13 European sites were enrolled in the C3 European module of GREAT. The patient demographics and risk factors have already been presented in a previous paper and are summarized in Table 1.[14] Results from 74 of these patients have also been included in a previously published report originating from one of the participating centers.[15]

Table 1. Patient demographics and risk factors.

Patient characteristics and risk factors	
Gender	$n = 400$
Male	86.8%
Female	13.3%
Age (yrs)	
Mean (SD)	73.9 (7.8)
Risk factors	
Hypertension	76.2%
Hypercholesterolemia	59.2%
Tobacco use	39.9%
Coronary artery disease	39.0%
Coronary artery bypass graft	13.3%
Congestive heart failure	7.8%
Peripheral arterial disease	22.6%
Chronic obstructive pulmonary disease	16.7%
Diabetes mellitus	13.4%
Renal insufficiency	11.8%
Renal dialysis	1.0%
Stroke	8.3%
Carotid disease	6.4%
ASA classification	
I	1.8%
II	34.8%
III	58.3%
IV	5.1%

Elective AAA was the most common indication for treatment (377/400, 94.3%), followed by common iliac artery aneurysm (13/400, 3.2%), ruptured AAA (6/400, 1.5%), aortocaval fistula (2/400, 0.5%), symptomatic 8-cm internal iliac artery aneurysm (1/400, 0.25%), and aorto-bi-iliac aneurysm (1/400, 0.25%).

In 393/400 (98.2%) patients, the C3 Excluder implantation was performed as a primary procedure. In the remaining cases, the C3 Excluder was used to repair aneurysms after prior open (3/400, 0.8%) or endovascular (4/400, 1%) aortic procedures.

The mean maximum aneurysm diameter was 59.9 ± 11.4 mm (range 24–110 mm). The proximal aortic neck had a mean length of 28.0 ± 14 mm (range 2–95 mm) and a mean angulation of 29.1 ± 24.4° (range 0–100°). Six patients had a neck length shorter than 10 mm. Four of them had a neck length of 9 mm, one of 3 mm, and one of 2 mm. The last two patients were both treated with bilateral renal chimney grafts. Sixty-eight (17%) patients were treated outside one or more IFUs for the C3 Excluder stent-graft.[14]

Operative data

The procedures were performed under general anesthesia in 90.5%, regional anesthesia in 9%, and local anesthesia in 0.5% of cases. Access was obtained via surgical cut-down in 288/400 (72%), percutaneously in 70/400 (17.5%), and with a combination of both techniques (1 groin open, 1 groin

percutaneous) in 42/400 (10.5%) of patients. A surgical conduit for access was needed in two (0.5%) cases. Median procedure duration was 120 minutes (range 50—667 minutes).

Intraoperative stent-graft repositioning and need for proximal cuff extender

Two hundred and seventy-nine repositioning maneuvers were performed in 192/399 (48.1%) patients. The most frequently reported (69%) reason for repositioning was level readjustment with regard to the renal arteries, followed by contralateral gate reorientation (17%). Other less frequently reported reasons for repositioning (14%) mainly included intentional initial deployment above the renal arteries to facilitate catheterization of the contralateral gate within a previous stent-graft, and intentional twisted limb positioning after successful catheterization of the contralateral gate. The mean number of repositionings performed per case was 1.5 $\pm$ 0.7. One repositioning maneuver was performed in 123/192 (64%), two in 54/192 (28.1%), three in 12/192 (6.3%), and four in 3/192 (1.6%) patients. The exact final position, according to the implanting physician, was achieved in 96.2% of patients, and within 5 mm of the intended position in an additional 1.5% of patients. Table 2 summarizes stent-graft repositioning data.

Adjunctive proximal cuff extender implantation was required in 21/398 (5.3%) patients. In 19 (4.8%) patients, implantation of the proximal cuff was unplanned. The main reason for unplanned proximal cuff use was treatment of type I endoleak ($n = 9$), increase of sealing zone ($n = 5$), increase of radial force ($n = 3$), and extension of landing zone ($n = 2$).

Perioperative outcome

Technical success was achieved in 396/400 (99%) patients. Two patients needed intraoperative open conversion, one for iliac rupture, the second because the stent-graft was pulled down during a cross-over catheterization in an angulated anatomy. Two patients required an unplanned chimney renal stent to treat partial coverage of the left renal artery due to stent-graft upward displacement. In one patient the stent-graft was displaced upwards due to excessive upward readjustment of the ipsilateral limb to preserve the hypogastric artery. In the second patient, the stent-graft migrated proximally during advancement of an iliac limb. There were no intraoperative deaths.

The thirty-day mortality was 2 (0.5%) patients. One patient died of respiratory failure, and one due to cardiac failure. The intensive care unit (ICU) admission rate was 96/400 (24%). Median hospital stay including a preoperative admission day was 5 days (range 1—53 days). Peri-operative procedure-related serious adverse events were noticed in 29/400 (7.3%) patients (Table 3). There was one (0.3%) device-related serious adverse event: an ipsilateral limb-graft appeared to be twisted after extensive reorientation during the procedure for contralateral gate cannulation, which resulted in an asymptomatic stenosis. The limb was stented preventively after 2 months. Early ($\leq$30 days) reintervention was required in two (0.5%) patients. Both patients had a significant stenosis of an iliac limb-graft due to extreme kinking of the common iliac artery and underwent prophylactic stent relining. No stent-graft migration was observed within 30 days of the procedure.

Follow-up

Mean follow-up duration was 15.9 $\pm$ 8.8 months (range 0—37). Twenty-eight patients died during follow-up: 26 due to aneurysm unrelated causes and two due to unknown cause. Cumulative patient survival as estimated by Kaplan—Meier was 96% (95% CI 93.3—97.6%) and 90.6% (95% CI 85.6—93.9%) at 1 and 2 years, respectively (Fig. 1). No patients required conversion to open repair during follow-up. No stent-graft migration was noticed in any patient during follow-up.

Aneurysm sac shrinkage (>5 mm) during follow-up was noticed in 36% of the patients, stable aneurysm diameter (−5 to +5 mm) was seen in 59%, and aneurysm sac growth in 5%. Overall, the mean aneurysm diameter decreased from 59.9 $\pm$ 11.4 mm to 53.7 $\pm$ 10.3 mm ($p < .001$).

Late reintervention (>30 days) was performed in 26 cases. Sixteen reinterventions were performed for endoleak. These included 12 type II endoleaks treated with coil/onyx embolization, two type Ia endoleaks (both in outside IFU necks) treated with proximal cuff implantation, and two type Ib endoleaks treated with limb-graft extension. Two of six chimney stents needed reintervention, one for stenosis treated with stent extension and one for acute occlusion treated with recanalization and stenting. Three iliac occlusions were treated, two within the iliac limb-graft, and one

Table 2. Summary of proximal trunk repositioning data.

Number of patients reporting trunk repositioning	192/399 (48.1%)
Reasons for repositioning	
Positioning closer to renal arteries	67%
Contralateral gate positioning	19%
Other	14%
Mean (SD) repositions per case	1.5 (0.7)
Number of repositions per case	
1	123 (64%)
2	54 (28.1%)
3	12 (6.3%)
4	3 (1.6%)

Table 3. Summary of perioperative serious adverse events.

Number of subjects enrolled	400
Any serious event	29 (7.3%)
Lower limb ischemia	3 (0.8%)
Pulmonary complications	4 (1%)
Pulmonary embolism	2 (0.5%)
Cardiac complications	2 (0.5%)
Device related adverse events	1 (0.3%)
Ischemic stroke	1 (0.3%)
Renal complications	6 (1.5%)
Post procedural hemorrhage	2 (0.5%)
Other	8 (2%)

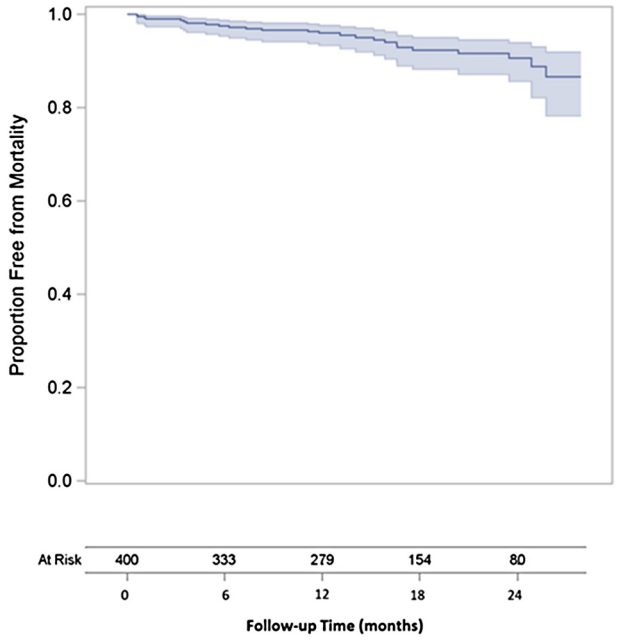

Figure 1. Kaplan—Meier estimate of cumulative patient survival during follow-up. The grey area above and below the centerline represents the 95% CI.

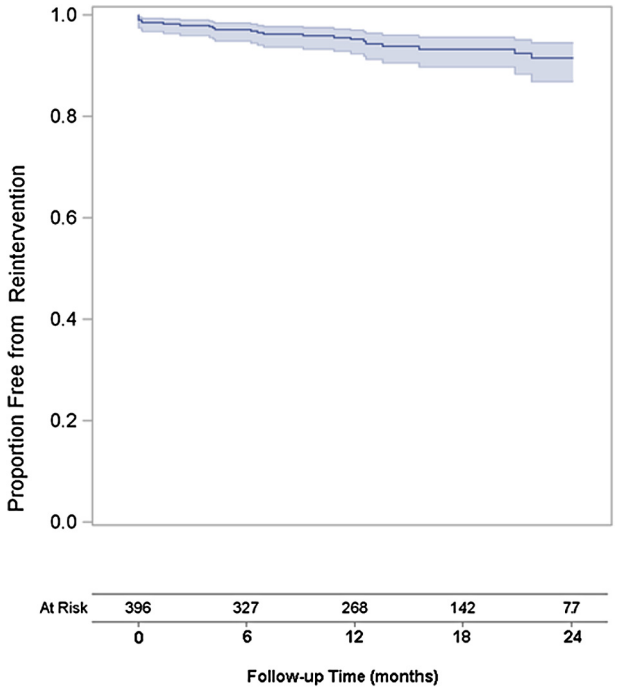

Figure 2. Kaplan—Meier estimate of freedom from reinterventions during follow-up. The grey area above and below the centerline represents the 95% CI.

in the native external iliac artery. An additional two iliac limb-graft stenoses (1 due to twisting, 1 due to kinking) were treated with preventive stenting. One reintervention was carried out to treat a femoral artery pseudoaneurysm. One patient with an inadequate proximal seal due to neck dilatation, but without clear proximal endoleak, was admitted with a rupture after being involved in a road traffic accident as a passenger. He was treated with a cuff in the acute situation, and later with another cuff with three chimneys, and is still alive. In the last patient, the stent-graft main body collapsed in an angulated neck. This was treated with a Palmaz stent. Estimated freedom from reintervention at 1 year was 95.2% (95% CI 92.3—97%), and at 2 years 91.5% (95% CI 86.8—94.5%) (Fig. 2).

DISCUSSION

Since the introduction of EVAR, stent-graft manufacturers have been improving device technology with the aim of improving long-term durability, but also to expand anatomic eligibility. To evaluate new devices, randomized controlled trials, although providing the highest scientific level of evidence, do present disadvantages including slow patient recruitment, prolonged study period, and often poor generalizability and clinical relevance of the findings. High-volume observational studies in the form of registries may better reflect the real-world performance of new devices.[16] This is the reason why W.L. Gore have sponsored a registry with the new C3 Gore Excluder stent-graft in Europe.

Early outcomes of the first 400 patients of the European C3 module of GREAT reveal excellent real-world performance of the new C3 Gore Excluder stent-graft, with a very low surgical mortality and high technical success. Proximal trunk repositioning was performed in almost half of the patients, mostly for level readjustment in relation to the renal arteries. This resulted in a high rate (96.2%) of accurate proximal deployment of the stent-graft and low use (4.8%) of unplanned proximal cuff-extenders, which was lower than older EVAR series.[17,18] Long-term follow-up will show whether more accurate proximal positioning also leads to better long-term results.

The new C3 deployment mechanism provides several options for readjustment of the Excluder stent-graft, which can be used in different scenarios.[13,19] The ability to reposition the device for proximal level enables accurate deployment in relation to the renal arteries as shown above. This proves beneficial both for inexperienced users (second and third chance for accurate deployment), and for experienced users in cases with challenging neck anatomy. The option to adjust the orientation of the contralateral gate could be used to facilitate catheterization. The ipsilateral limb deployment is a separate step, which may allow the limb to be pushed upwards during slow, controlled deployment. This could avoid inadvertent overstenting of the hypogastric artery.[19] This maneuver is not described in the IFU and should be performed with caution.

The IFU advises a maximum of two repositionings, but the registry data show that repositioning was safely repeated up to four times. No device-related failure, aortic tear, dissection, or distal embolization was recorded in 192 patients with 279 repositioning maneuvers. Nevertheless, risks associated with excessive repositioning are inherent. Reconstraining the stent-graft and upward level repositioning may be difficult in narrow, long, and/or angulated neck anatomy due to increased friction. In this type of adverse anatomy, the stent-graft should be deployed

aggressively at the level of the renal arteries or even somewhat higher, with the option to pull it down if needed. Excessive rotational reorientation may occasionally cause twisting of the ipsilateral limb. When reorienting the graft to facilitate limb catheterization, later ipsilateral limb deployment should be done slowly under continued fluoroscopy. This enables de-rotating the limb to avoid twisting. Finally, excessive upward readjustment of the ipsilateral limb, aiming to avoid hypogastric artery overstenting, could result in upward migration of the proximal trunk, as experienced in one case.[19] Attention should therefore be paid to ensure that the proximal edge of the stent-graft remains in position during pushing-up of the ipsilateral limb to readjust its length. Alternatively, an inflated balloon within the body of the stent-graft inserted from the contralateral side would probably prevent upward migration during readjustment of the ipsilateral limb.

Seventeen percent of the patients were treated outside the IFU for the C3 Excluder. Delivery; positioning and deployment of the stent-graft were not affected. Technical success and stent-graft deployment accuracy remained high as previously published, but two type Ia endoleaks occurred during early follow-up, requiring reintervention.[14] Therefore, it should not be advocated to treat shorter necks, especially if other options such as fenestrated grafting are possible.

During follow-up, a stent-graft body collapse occurred 4 months after implantation causing acute onset of claudication. This occurred in a patient with a long angulated neck. At the end of the initial procedure, the C3 Excluder clearly lacked perfect apposition, despite repeated ballooning. The graft collapsed into a crescent shape with a very small lumen. Treatment was successful with implantation of a Palmaz stent. A similar problem has incidentally been reported with the old Excluder stent-graft.[20]

Late reintervention (>30 days) was required in 26 (6.5%) patients during follow-up, with estimated freedom from reintervention at 1 year of 95.2% (95% CI 92.3—97%). These reintervention rates are relatively high, but comparable with previously published registries of other contemporary stent-grafts.[21] The most common reason for reintervention was endoleak repair. The high rate of type II endoleak repair (46.2% of all reinterventions) should be taken into account when looking at the overall reintervention rates. This probably reflects an overall trend towards more aggressive treatment of type II endoleaks. Reintervention for limb-graft occlusion was very low (0.5%), which confirms the excellent performance of Excluder limb-grafts, even in difficult iliac anatomies.[22]

Recently, the early results of the ENGAGE registry were published, showing promising real-world performance of the Endurant stent-graft (Medtronic Endovascular, Santa Rosa, CA, USA) in the short term. Early results of the C3 Excluder are comparable to the results of the ENGAGE registry in terms of initial technical success (both 99.0%), 30-day mortality (0.5% GREAT vs. 1.3% ENGAGE), and estimated patient survival at 1 year (96% GREAT vs. 91.6% ENGAGE). Estimated freedom from reintervention at 1 year was also similar between the two registries (95.2% GREAT vs. 95.1% ENGAGE), although different trends in the leading reasons for reintervention were shown (Type II endoleaks for C3 Excluder, iliac limb-graft occlusions for ENGAGE).

Limitations of the present study should be acknowledged. Data, although prospectively collected, were retrospectively analyzed. Follow-up schemes and reintervention protocols differed between centers. Selection bias is also inherent due to the observational design of the study. Finally, follow-up time in this registry is still limited, precluding firm conclusions on the impact of the new C3 deployment mechanism on long-term durability.

CONCLUSIONS

Real-world performance as reflected by the European C3 module of GREAT indicates that the new C3 Excluder stent-graft offers excellent early and short-term outcome. Graft repositioning was used in almost 50% of cases, with excellent results in terms of accurate proximal position. The reorientation option was also used with success, but less frequently. Longer follow-up is needed to confirm these results, and to prove that more accurate proximal position of the stent-graft results in better EVAR durability and reduced need for reintervention.

CONFLICT OF INTEREST

Eric L.G. Verhoeven has received educational grants and is a consultant for Cook Inc., W.L. Gore & Associates, Siemens and Atrium-Maquet. Hence Verhagen is a consultant for W.L. Gore & Associates and Medtronic. Thomas Larzon has received educational grants from W.L. Gore & Associates. Dittmar Böckler has received speaker fees and is a consultant for W.L. Gore & Associates.

FUNDING

GREAT was funded by W.L. Gore & Associates.

REFERENCES

1 De Bruin JL, Baas AF, Buth J, Prinssen M, Verhoeven EL, Cuypers PW, et al. Long-term outcome of open or endovascular repair of abdominal aortic aneurysm. *N Engl J Med* 2010;**362**:1881—9.
2 Prinssen M, Verhoeven EL, Buth J, Cuypers PW, van Sambeek MR, Balm R, et al. A randomized trial comparing conventional and endovascular repair of abdominal aortic aneurysms. *N Engl J Med* 2004;**351**:1607—18.
3 AbuRahma AF, Campbell J, Stone PA, Nanjundappa A, Jain A, Dean LS, et al. The correlation of aortic neck length to early and late outcomes in endovascular aneurysm repair patients. *J Vasc Surg* 2009;**50**:738—48.
4 Katsargyris A, Verhoeven EL. Endovascular strategies for infrarenal aneurysms with short necks. *J Cardiovasc Surg (Torino)* 2013;**54**:21—6.
5 Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. *Ann Vasc Surg* 1991;**5**:491—9.
6 Volodos NL, Karpovich IP, Troyan VI, Kalashnikova Yu V, Shekhanin VE, Ternyuk NE, et al. Clinical experience of the use

of self-fixing synthetic prostheses for remote endoprosthetics of the thoracic and the abdominal aorta and iliac arteries through the femoral artery and as intraoperative endoprosthesis for aorta reconstruction. *Vasa* 1991;**33**:93—5.
7 Fillinger M. Three-dimensional analysis of enlarging aneurysms after endovascular abdominal aortic aneurysm repair in the Gore Excluder Pivotal clinical trial. *J Vasc Surg* 2006;**43**:888—95.
8 Haider SE, Najjar SF, Cho JS, Rhee RY, Eskandari MK, Matsumura JS, et al. Sac behavior after aneurysm treatment with the Gore Excluder low-permeability aortic endoprosthesis: 12-month comparison to the original Excluder device. *J Vasc Surg* 2006;**44**:694—700.
9 Hogg ME, Morasch MD, Park T, Flannery WD, Makaroun MS, Cho JS. Long-term sac behavior after endovascular abdominal aortic aneurysm repair with the Excluder low-permeability endoprosthesis. *J Vasc Surg* 2011;**53**:1178—83.
10 Bos WT, Tielliu IF, Van Den Dungen JJ, Zeebregts CJ, Sondakh AO, Prins TR, et al. Results of endovascular abdominal aortic aneurysm repair with selective use of the Gore Excluder. *J Cardiovasc Surg (Torino)* 2009;**50**:159—64.
11 Lee CJKM, Morasch MD. Gore excluder device with the C3 delivery system for management of abdominal aortic aneurysm. *Open Access Surg* 2012;**5**:15—21.
12 Chaikof EL, Brewster DC, Dalman RL, Makaroun MS, Illig KA, Sicard GA, et al. The care of patients with an abdominal aortic aneurysm: the Society for Vascular Surgery practice guidelines. *J Vasc Surg* 2009;**50**:2—49.
13 Verhoeven EL, Oikonomou K, Mohner B, Renner H, Ritter W. First experience with the new repositionable C3 excluder stent-graft. *J Cardiovasc Surg (Torino)* 2011;**52**:637—42.
14 Bachoo P, Verhoeven EL, Larzon T. Early outcome of endovascular aneurysm repair in challenging aortic neck morphology based on experience from the GREAT C3 registry. *J Cardiovasc Surg (Torino)* 2013;**54**:573—80.
15 Katsargyris A, Botos B, Oikonomou K, Pedraza de Leistl M, Ritter W, Verhoeven EL. The new C3 Gore Excluder stent-graft: single-center experience with 100 patients. *Eur J Vasc Endovasc Surg* 2014;**47**:342—8.
16 Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. *Lancet* 2003;**362**:1225—30.
17 Biebl M, Hakaim AG, Lau LL, Oldenburg WA, Klocker J, Neuhauser B, et al. Use of proximal aortic cuffs as an adjunctive procedure during endovascular aortic aneurysm repair. *Vascular* 2005;**13**:16—22.
18 Aburahma AF, Campbell JE, Mousa AY, Hass SM, Stone PA, Jain A, et al. Clinical outcomes for hostile versus favorable aortic neck anatomy in endovascular aortic aneurysm repair using modular devices. *J Vasc Surg* 2011;**54**:13—21.
19 Katsargyris A, Oikonomou K, Bracale UM, Verhoeven EL. Unexpected complication with the new C3 Excluder: cause and treatment. *Cardiovasc Intervent Radiol* 2013;**36**:536—9.
20 Maleux G, Claes H, Van Holsbeeck A, Janssen R, Laenen A, Heye S, et al. Ten years of experience with the Gore Excluder stent-graft for the treatment of aortic and iliac aneurysms: outcomes from a single center study. *Cardiovasc Intervent Radiol* 2012;**35**:498—507.
21 Stokmans RA, Teijink JA, Forbes TL, Bockler D, Peeters PJ, Riambau V, et al. Early results from the ENGAGE registry: real-world performance of the Endurant Stent Graft for endovascular AAA repair in 1262 patients. *Eur J Vasc Endovasc Surg* 2012;**44**:369—75.
22 Bos WT, Tielliu IF, Sondakh AO, Vourliotakis G, Bracale UM, Verhoeven EL. Hybrid endograft solution for complex iliac anatomy: Zenith body and Excluder limbs. *Vascular* 2010;**18**:136—40.